Kansas Medical Assistance Program

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

May 11, 2005

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas May 11, 2005	**Members Present:** Michael Burke, M.D., Ph.D., Chair; Dennis Grauer, Ph.D.; Linda Kroeger, ARNP; John Lowdermilk, R.Ph.; Barry Sarvis, R.Ph.; Brenda Schewe, M.D.; Kevin Waite, PharmD **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A.; Mary Obley, R.Ph.; Anne Ferguson, R.Ph., DUR Program Director; Erica Miller **EDS Staff Present:** Karen Kluczykowski, R.Ph.; Deb Quintanilla, R.N.	**Representatives:** Craig Boon (ACS Heritage), Patty Laster (Genentech), Bruce Kirby (Genentech), Ann Gustafson (GlaxoSmithKline), Dr. Wayne Moore (Children's Mercy Hospital), Michael Waljie (AstraZeneca), Rhonda Clark (Purdue), Elizabeth Stoltz (Janssen), Joshua Lang (Novartis), James Dube (Purdue), Ronald Godsey (TAP), Mike Moratz (Merck), Tammy Shelor (Naplor), Patricia Solbach (Janssen), Eric Gardner (Wyeth), Tammie Capps (Purdue), Bob Twillman (KU Medical Center), Jon Snow (UCB Pharma), Dr. Kenneth Dykstra (Wichita), Jim Baumann (Pfizer)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:40a.m.	
II. Review and Approval of March 09, 2005, Meeting Minutes	• There was one correction made by Dr. Schewe, remove the by Phone from the Members Present by Phone.	• A motion to approve the minutes with the corrections was made by Dr. Schewe and seconded by Ms. Kroeger. The motion carried unanimously by roll call.
III. New Business **A. Heritage** **1. Outcomes**	• Craig Boon (ACS Heritage) presented data from the Pediatric Antidepressant Outcome targeted intervention. Data suggest improved treatment compliance resulting from the intervention. The DUR Board would also like to see the full medical impact of the intervention including changes in hospitalization rate.	
2. Intervention Recommendations	• Anne stated that the state would like to replace the psychiatric coordination of care intervention, since the state may be joining the Behavioral Pharmacy Management program through Comprehensive Neuroscience (CNS). Craig stated that he has brought two intervention proposals for replacing the psychiatric coordination of care	

TOPIC	DISCUSSION	DECISION/ACTION
Heritage – Con't	intervention. • Craig presented the Gabapentin Intervention proposal. Dr. Burke stated that he would like to see a paragraph included in the Gabapentin letter regarding the Oregon Evidence-based Policy report. • Craig presented the Drugs with Abuse Potential Intervention Proposal. This intervention would exclude cancer patients. Mr. Lowdermilk stated that he noticed that the Benzodiazepines are included on this intervention. The Benzodiazepine coverage has recently started, is there already an abuse problem. Anne stated that she had Craig leave the Benzodiazepines on because it could be an issue. • Dr. Burke stated that we plan to revisit the Benzodiazepines, so we can change coverage if there is over utilization and signs of abuse. He thinks the Gabapentin would be a better intervention. Dr. Waite asked if Craig has a dollar value estimate for the number of patients for the over utilization intervention. Craig stated that for this presentation he didn't, but another option is to do the Drug Abuse intervention as a patient profile review. • Dr. Schewe stated that most physicians know who their drug abuse patients are; agreed that Gabapentin would be a better intervention. • Mr. Lowdermilk stated that the expenditures for Gabapentin should start to go down, since a generic was released. Mary stated that the State thought this would be a good educational intervention due to the diagnosis code restriction policy that will be implemented. • With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Waite and seconded by Dr. Schewe for the Gabapentin Intervention to be the intervention that replaces the Psychiatric Coordination of Care Intervention. The DUR Board also recommended including a paragraph regarding the Oregon Evidence-based Policy report in the Gabapentin letter. The motion carried unanimously by roll call.
IV. Old Business **A. Growth Hormones (GH)** **1. Discussion of Prior Authorization Criteria**	• Anne reviewed the draft prior authorization (PA) criteria. She explained why the Stim tests were left on the draft.	

TOPIC	DISCUSSION	DECISION/ACTION
Growth Hormones – Con't **2. Endocrinologist Presentation**	• Dr. Dykstra (Wichita Endocrinologist) gave background information on how he became involved with the PA criteria. He did not agree with the exclusion of Prader Willi (PW), Short for Gestational Age (SGA), and Idiopathic Short Stature (ISS) on the last draft PA criteria. His biggest concern with the current PA draft is the guidelines ignore the growth chart and rely on laboratory values. The lab tests are most useful in saying this is what the patient is not, and he is concerned they have become an excuse to deny coverage. Recent reviews say that the stim tests are not ideal. He also does not agree with requiring a MRI for panhypopituitarism, it just shows a picture of the gland it does not prove if it works. He also expressed concern about the use of bone age to identify if growth is still possible. He has seen children grow even with advanced bone age, if the child is growing then plates are still open. The IGF-1/IGFBP3 is not by any means a perfect test and should be used as a screening test. He felt the PA draft relies on lab tests and lab tests may be the standard, but standards can be changed. SGA and ISS are quoted as being cosmetic, if SGA and ISS are considered cosmetic then in his opinion Prader Willi (PW), Turner Syndrome (TS), and Chronic Renal Insufficiency (CRI) should be as well. In these cases he believes GH is given only to improve height. CRI patients have limited stature, GH does not help the kidney disease, only height. SGA patients have a cause for not growing we're just not sure what the cause is. Regarding the letter given to the DUR Board at the last meeting, I'm not sure what benefits SGA kids would have with GH regarding diabetes. Dr. Dykstra argued for the inclusion of ISS and SGA or exclusion of TS, CRI, and PW. There should be guidelines not criteria that meet everyones needs and it should be flexible and allow feedback. He would like to recommend having a checklist sent to physicians saying why a particular patient is denied GH. • Dr. Grauer stated that Dr. Dykstra suggests there should be a checklist, but Dr. Dykstra earlier stated it is hard to create a checklist. Dr. Dykstra stated that if I have a checklist in hand and see the patient hasn't passed the GH test I know they won't be approved, but I prefer not to practice from a checklist. There should be a growth velocity chart as opposed to growth velocity. With growth velocity, you have to have a poorer growth in younger ages	

TOPIC	DISCUSSION	DECISION/ACTION
Growth Hormones – Con't	than in older. • Dr. Burke expressed the boards understanding of the point made by Dr. Dykstra that to be meaningful growth velocity needs to be normalized to the child's age. Dykstra stated that a lot of children meet the criteria for SGA without the stim tests based on growth velocity charts. The lab tests are not reproducible and do not correlate with each other.	
3. Public Comment	• Dr. Wayne Moore (Children's Mercy Hospital) stated that he mostly agrees with Dr. Dykstra's comments. His office is located in Missouri, but they have an office in Kansas. He suggested that there are benefits of GH in all kids besides effects on stature. GH effects linear growth, bone, muscle, and fat. All the clinical effects of GH are still not well understood. Patients with GH deficiency have abnormalities in all areas. GH affects other things besides height in TS & CRI. In muscle it improves strength, mass, and endurance. In bone it improves bone mass and density. ISS research is coming out in which they suspect an abnormality of GH. It is called idiopathic because we don't yet know what is wrong in ISS patients. Regarding cost issue, we surveyed our kids, for SGA we added 14 children and 40-50 kids for ISS. Actual population of SGA and ISS patients is rather small. There are no alternative choices besides GH. • Ms. Kroeger asked if fat, bone, and muscle benefit from GH treatment, do benefits continue if GH is stopped. Dr. Moore stated that most severe cases need to continue treatment for life. I'm not sure if GH patients need to be treated as adults for borderline GH deficiencies, best indication is to see if GH works. • Dr. Schewe asked how long of a trial do you think patients need in order to know if GH will be beneficial. Dr. Moore suggested 6 months to a year, that is what Australia has found to have the best result. Dr. Schewe pointed out that the total pharmacy budget is $200,000,000, if all ISS and SGA patients try GH it could increase the budget to $600,000,000. Which patients are we not going to cover if we allow GH therapy experimental trials. Dr. Moore stated that he does not think those numbers are accurate. In his practice, they only have 40 kids that are diagnosed with ISS or SGA. Anne stated that we retrieved those numbers from our system. Dr. Moore stated that SGA kids are probably only 10% of all kids. Dr. Dykstra stated that those	

TOPIC	DISCUSSION	DECISION/ACTION
Growth Hormones – Con't	aren't all patients that need treatment. There are growth deficient kids that are not short. • Ms. Kroger asked Dr. Dykstra if he would recommend basing the GH PA criteria on growth velocity. Dr. Dykstra answered yes. • Dr. Burke stated that it would be helpful to see Dr. Moore's recommended criteria. Dr. Moore stated that we should use the FDA approved indications as our criteria. • Dr. Grauer asked Dr. Moore, out of your practice how many total kids do you treat with GH. Dr. Moore stated that 14 are SGA, 8 out of the 14 SGA patients were GH deficient and 40 are ISS. Dr. Grauer asked out of how many total patients. Dr. Moore stated that he is not sure, maybe around 1000. • Ms. Kroeger asked out of the 40 ISS patients how many are responding to GH treatment. Dr. Moore stated that whether you decide to continue GH treatment or not the patient will show catch up growth. • Nialson asked Dr. Moore if he agrees with Dr. Dykstra that ISS, SGA, TS, PW, and CRI are all cosmetic. Dr. Moore stated that he doesn't. Cosmetic is usually an excuse to not pay. • Dr. Moore stated that there is eventually going to be an explanation for patients that are ISS. Mary stated that long term risks should be a consideration. Dr. Moore stated that we are pretty familiar with risks, we are replacing something they are missing. Mary stated that is if they are indeed GH deficient.	
4. SRS Comments	• Anne reviewed the Other State Coverage handout. • Anne stated that we wish we could cover GH for everyone, but it is not logical. We don't want to decline coverage for PW, CRI, and TS as they have an active disease. ISS is an issue of height in otherwise apparently healthy kids. SGA if they do not have GH deficiency is also an issue of height. In our research we could not find proof of any long term effects that show they will have a better outcome if they are on GH. Our estimate of the cost increase is the worst case scenario, currently there are 26,000 patients that had a diagnosis of SGA or ISS in 2004. We have a limited budget and we would be shifting funds away from primary care.	

TOPIC	DISCUSSION	DECISION/ACTION
Growth Hormones – Con't	• Dr. Grauer asked why we can't restrict for patients that need GH to see an endocrinologist. Dr. Dykstra stated that the management of GH is made by an endocrinologist. The nephrologist sends patients that need GH to an endocrinologist. Dr. Schewe stated that it sounds like all GH patients should be sent to an endocrinologist. • Dr. Burke asked if we could have the pharmaceutical companies provide the 6 month trials of GH. Dr. Dykstra stated that if he has a patient that is denied GH he sends multiple letters, he exhausts all possibilities. Not sure if having the pharmaceutical companies provide the trials is a good idea. • Dr. Burke stated that it sounds like 10% of the patients with a SGA or ISS diagnosis would be eligible for GH, that is still an increase of around 60 million a year. Dr. Waite stated that it might be better to assume 5% would be eligible. • Dr. Burke stated that the problems are that the endocrinologist are not satisfied with the draft PA criteria. And there isn't a true appeals process. Do we want to take this back and try redrafting with an appeal process. Mary explained that there is an appeals process, not all appeals are denied. The appeal that Dr. Dykstra attended was approved. The appeals office stated that witnesses can testify by phone, if the provider filed the appeal then they have to attend. Dr. Burke stated that we need data on how many PAs are rejected and how many total appeals there are. Deb Q (EDS) stated that in the last 6 months, 75 PAs have been sent in. 35 are renewals and 37 are new. 37 approved, 32 denied, 2 appealed and approved, 1 appealed and is pending, and 1 appealed and then cancelled. • Dr. Burke stated that perhaps GH appeals should be addressed on two levels, doesn't meet criteria and then a second level appeal. He stated that Dr. Dykstra made a compelling argument that growth velocity needs to be normalized by age and sex, and suggested we should try re-crafting the PA criteria one more time. • Dr. Burke asked about patients with open epiphyseal plates, once epiphyseal plates are closed what happens, do you continue treatment. Dr. Dykstra stated that if they stop growing you continue them on GH if they are GH	

TOPIC	DISCUSSION	DECISION/ACTION
Growth Hormones – Con't	deficient. If patient is GH deficient in childhood and not in adult hood, don't know if there are any results of continuing treatment. Dr. Moore stated that long term use of GH in SGA and ISS if not severely deficient will have results, but you may not see them for 40 to 50 years. Dr. Burke summarized Dr. Moore's comments by stating that although intuitively GH therapy would seem to offer many potential benefits, at present there is not significant scientific data to support a broad range of clinical benefits. • Dr. Burke stated that he would be happy to entertain a motion to rework the draft PA criteria and bring this back for a final review, this would not be for an extensive further discussion. • Mr. Sarvis stated that he thinks the PA could use some tweaking. Thinks that the appeals process is not that far off from what it should be. So far there have been 4 appeals, 2 approved, 1 cancelled, and 1 pending. This is a pretty good approval rate. Dr. Grauer stated that he agrees and that the PA can be reworded, but it sounds like it will still come down to SGA and ISS. • Dr. Moore stated that Dr. Dykstra and I would be willing to work with KS Medicaid on the draft criteria. • Mary stated that Dr. Dykstra helped on the criteria that was brought to the last meeting, then we received a letter at the meeting stating that he denied it. Dr. Dykstra stated that he would like to clarify that his name should not have been on the letter denying the criteria. • Mary clarified that the growth velocity chart can be used. Dr. Dykstra stated the growth velocity or a growth chart should be used. • Dr. Burke reviewed the differences between the two recent drafts of the PA criteria for GH as a point of departure for another attempt at reworking the criteria.	
5. DUR Board Recommendations	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Waite and seconded by Dr. Schewe to table growth hormones until another attempt is made to update the PA criteria which should include input from appropriate specialist. The motion carried unanimously by roll call.

TOPIC	DISCUSSION	DECISION/ACTION
II. New Business – Con't **B. Elidel® & Protopic®** **1. Discussion of Prior Authorization Criteria**	• Anne reviewed the proposed PA criteria based on the FDA health advisory and manufacturer labeling.	
2. Public Comment	• Josh Lang (Novartis) presented information to the DUR Board regarding Elidel®. Mr. Lang stated that Novartis does not agree with the FDA's decision.	
3. DUR Board Recommendation	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Grauer and seconded by Ms. Kroeger to accept the SRS recommended criteria. The motion passed with Dr. Schewe voting no and the rest voting yes.
C. Palladone® **1. Discussion of Prior Authorization Criteria**	• Anne reviewed the SRS recommended PA criteria. The criteria is based on the manufacturer labeling. #5 has been added to the PA criteria, quantity limit of one dosage unit per day per NDC, this was added at the request of the manufacturer, Purdue Pharma. This is a new drug, there have only been 9 claims to date. One of the nine claims did not meet criteria set forth in package labeling.	
2. Public Comment	• James Dube (Purdue Pharma) presented information to the DUR Board regarding Palladone®.	• A motion was made by Dr. Schewe and seconded by Dr. Waite to accept the SRS recommended criteria with the addition of #5 quantity limit of 1 dosage unit per day per NDC. The motion carried unanimously by roll call.
3. DUR Board Recommendation	• With no further board discussion, a motion was placed before the board.	
D. Proton Pump Inhibitors – Greater than One Unit a Day Prior Authorization **1. Discussion of Prior Authorization Criteria**	• Anne reviewed the SRS recommended PA criteria. This is the exact same criteria that was in place prior to the PDL PA. The PA was removed when the PDL PA went into affect. A review of the historical data shows that 23% of the PAs were denied. Currently 11% of the claims are for a dose greater than 1 a day. Anne reviewed 10 other states, 6 currently have some restrictions. • Dr. Schewe stated that anyone can have GERD, this would allow anyone to be approved, number 1 should be removed. It should be standard practice to re-evaluate after 60 days of high dose. Dr. Waite agreed to remove number one from the criteria. This would encourage doctors to lower dose. • Mary stated that most likely the physician writes the prescription for the high amount and when the patient or	

TOPIC	DISCUSSION	DECISION/ACTION
Proton Pump Inhibitors – Con't	pharmacist calls to have the prescription refilled the physicians approves. • Karen K. (EDS) suggested removing the asterisks that are next to the non-PDL drugs and place a generic statement below the drug list. This will make it easier when the non-PDL drugs change.	
2. Public Comment	• Patricia Solbach (Janssen-Ortho McNeil) presented information to the DUR Board regarding PPIs. • Mike Waljie (AstraZeneca) presented information to the DUR Board regarding Nexium®.	
3. DUR Board Recommendation	• With no further board discussion, a motion was placed before the board.	• A motion was made by Dr. Schewe and seconded by Mr. Sarvis to accept the SRS recommended criteria with the removal of number 1 and the addition of the generic statement about non-PDL drugs requiring PDL PA. The motion carried unanimously by roll call.
E. Announcements	• Anne announced that this will be John Lowdermilk's last meeting. We appreciate his service to the DUR Board.	
V. Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Dr. Waite to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 12:15 a.m.